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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,269	07/19/2005	Fabio Giannessi	2801-140	1068

23117 7590 07/31/2007  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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CUTLIFF, YATE KAI RENE

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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07/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/537,269	Applicant(s) GIANNESI ET AL.	
	Examiner Yate K. Cutliff	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/01/2005</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on May 16, 2007 is acknowledged.

2. Claims 1-5, 7-9, and 13 –16 are pending.

Claims 6 and 10-12 have been canceled

Claims 13-16 are withdrawn from consideration as being drawn to the nonelected Invention.

Claims 1, 4, 5 and 7-9, in part embraced in elected subject matter of Group I, and Claim 2 are being prosecuted in this case.

Claims 1, 4, 5 and 7-9, in part, not embraced in the above elected subject matter, and claim 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

The requirement is still deemed proper.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on December 17, 2002. It is noted, however, that applicant has not filed a certified copy of the IT RM 2002A000625 application as required by 35 U.S.C. 119(b).

### ***Specification***

4. The abstract of the disclosure is objected to because it was not submitted on a separate sheet. Correction is required. See MPEP § 608.01(b).

**Claim Rejections - 35 USC § 102**

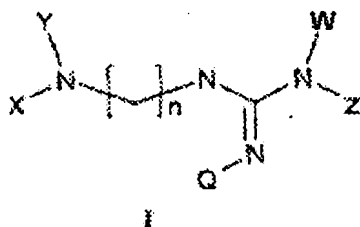
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

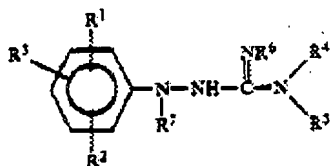
6. Claims 1, 2, 7, 8 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,731,383 to Erczi et al.

Applicant claims a compound of the following formula:



with n, Q, W, X, Y and Z as defined in claim 1.

Erczi et al. discloses aminoguanidine having the following formula (I):



Erczi et al. anticipates Applicant's claims when the R substituents of Erczi et al. are R1-  
R3 = halogen, R4 – R5 = C<sub>1-4</sub> alkyl, and R7= H. Specifically, when Applicant's n = 0,

Art Unit: 1621

Erczi et al. anticipates the claimed invention. Please note that the compound itself reads on the pharmaceutical compositions claims.

***Claim Objections***

7. Claims 4 and 5 are objected to for encompassing non-elected subject matter.

***Allowable Subject Matter***

8. Compounds where n is equal to 4-7 would be allowable if rewritten in independent form. The following is a statement of reasons for the indication of allowable subject matter: The guanidine derivatives of claim 4 is not taught or suggested by the prior art references.

9. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

10. The reference WO 97/23203, cited on Form 892 is included as informational.

***Conclusion***

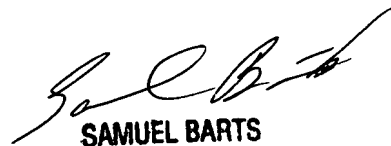
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yate K. Cutliff whose telephone number is (571) 272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 - 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yaté K. Cutliff  
Patent Examiner  
Art Unit 1609, Group  
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**SAMUEL BARTS**  
**PRIMARY EXAMINER**  
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